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ATTORNEY DOCKET NO. APPLICATION NO. CONFIRMATION NO. FIRST NAMED INVENTOR FILING DATE 10/662,756 REG 660AZ-US 09/15/2003 2302 Aris N. Economides **EXAMINER** 26693 7590 09/03/2004 REGENERON PHARMACEUTICALS, INC ANDRES, JANET L 777 OLD SAW MILL RIVER ROAD **ART UNIT** PAPER NUMBER TARRYTOWN, NY 10591 1646

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applic	ation No.	Applicant(s)	
Office Action Summary		10/66	2,756	ECONOMIDES ET AL.	
		Exam	ner	Art Unit	
		Janet	L. Andres	1646	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠ Responsi	ve to communication(s) fil	ed on <u>01 June 200</u>	<u>4</u> .		•
2a)⊠ This actio	his action is FINAL . 2b) This action is non-final.				
· ·	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Cla	ims				
 4) Claim(s) 1 and 4-11 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 1,6 and 8-11 is/are allowed. 6) Claim(s) 4, 5, 7 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 					
Application Papers					
9) The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
<u> </u>	erson's Patent Drawing Review (osure Statement(s) (PTO-1449 o	•	4) Interview Summa Paper No(s)/Mail 5) Notice of Informal 6) Other:	• •	O-152)

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RESPONSE TO AMENDMENT

1. Applicant's amendment filed 1 June 2004 is acknowledged. Claims 1 and 4-11 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

- 2. The objection to the specification is withdrawn in response to Applicant's amendment updating the priority data.
- 3. The rejection of claim 4 under 35 U.S.C. 101 as being drawn to non-statutory subject matter is withdrawn in response to Applicant's amendment to the claim.
- 4. The rejection of claims 1 and 3 under 35 U.S.C. 102(a) as anticipated by Saegusa et al. is withdrawn in response to Applicant's cancellation of claim 2 and amendment to claim 1.
- 5. The rejection of claims 10 and 11 under 35 U.S.C. 103(a) as unpatentable over Saegusa et al. in view of Ashkenazi et al. is withdrawn in response to Applicant's amendment to claim 1.
- 6. The rejection of claims 3, 12, and 13 under 35 U.S.C. 112, first paragraph, as lacking enablement or written description is withdrawn in response to Applicant's cancellation of these claims.
- 7. The rejection of claims 1, 3-7, and 9-13 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in response to Applicant's cancellation of claims 3, 12, and 13 and amendment to claim 1.

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Claim Rejections Maintained

8. The rejection of claims 4, 5, and 7 under 35 U.S.C. 103(a) as unpatentable over Saegusa et al. in view of Harlow and Lane is maintained for reasons of record in the office action of 28 April 2004.

Applicant has amended claim 1 so that it encompasses only SEQ ID NO: 12. Applicant additionally argues that the combined references fail to suggest the antigen against which the antibody is directed.

Applicant's arguments have been fully considered but have not been found to be persuasive. The protein taught by the prior art is 95% identical to that instantly claimed. Antibodies raised against that protein would bind specifically - that is, saturably, competably, and with high affinity, to instant SEQ ID NO: 12. Such binding would be an inherent property of an antibody raised against a closely related molecule; the antibody need not have been raised against the protein of SEQ ID NO: 12 itself in order to bind specifically to it.

CLAIMS 1, 6, AND 8-11 ARE ALLOWED. CLAIMS 4, 5, AND 7 ARE REJECTED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres. Ph.D. 1 September 2004

JANET ANDRES
PRIMARY EXAMINER